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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,354	03/13/2001	M. Amin Amaout	00786-536001	1935
26161	7590	08/25/2005	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			HADDAD, MAHER M	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/805,354

Applicant(s)

ARNAOUT ET AL.

Examiner

Maher M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51-53 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 51-53 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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## RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 6/6/05, is acknowledged.
2. Claims 51-53 are pending and under consideration in the instant application.
3. The information disclosure statement (IDS) filed 6/3/05 fails to comply with 37 CFR 1.9(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.
4. In view of the amendment filed on 6/6/05, only the following rejections and objection are remained.
5. The amendment filed 2/15/02, stand objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention for the same reasons set forth in the previous Office Action mailed 12/3/04.

Applicant's arguments, filed 6/6/05, have been fully considered, but have not been found convincing.

Applicant state that it is unclear what aspect of the figure that the examiner believes is new matter. Applicant contends that it appears that the lines representing the electron density are rather faint, but they are visible in the submitted figure. Applicant submits that the formal drawing does not contain new matter.

However, the Examiner notes that the new electron density map of the C-terminal portions of  $\alpha 7$  from 11bA<sup>123-321</sup> structure is different than the originally filled electron density map, please see the attached comparison between the new (12/15/02) and original (3/13/01). Clearly, the difference is not faint lines representing the electron density. The whole figure is different.

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12/15/02

3/13/01

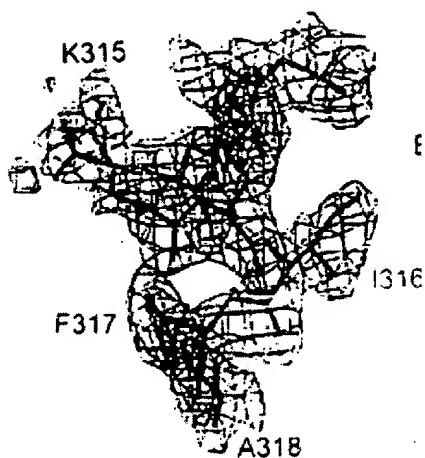
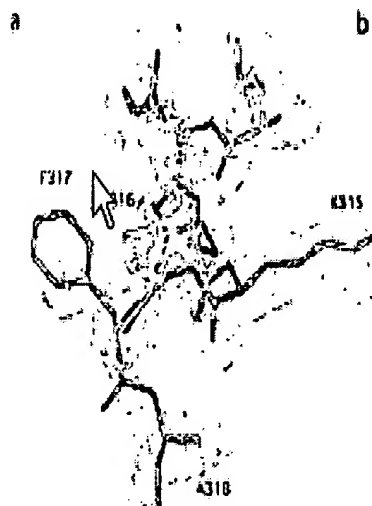


FIG. 2A



6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

7. Claims 51-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 1, wherein the Ile at amino acid 189 has replaced by amino acid Gly or Ala, does not reasonably provide enablement for a purified polypeptide "comprising the amino acid sequence of SEQ ID NO: 1, wherein the Ile at amino acid 189 has been replaced by any "amino acid" other than Ile in claim 51, wherein Ile at amino acid 189 has been replaced by Gly in claim 52 or Ala in claim 53. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 12/3/04.

Further, claim 51 recites the Ile at amino acid 189 has been replaced by "any amino acid", however, there is tremendous variability in the importance of individual amino acids in protein sequences. Since the A domain is a key determinants of activity of CD11b  $\alpha$  subunit, residue substitutions that are conservative (e.g., Glu in equilibrium Asp, Asn in equilibrium Asp, Ile in equilibrium Leu, Lys in equilibrium Arg and Ala in equilibrium Gly) can have severe phenotypic effects. There is no simple way to infer the likely effect of an amino acid substitution on the basis of sequence information alone. Therefore, one skill in the art would not be able to predicted what residue substitutions can replace Ile at position 332 of CD11b  $\alpha$  subunit besides Gly and

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Ala.

Applicant's arguments, filed 6/6/05, have been fully considered, but have not been found convincing.

Applicant asserts that the present application provides a detailed description of the preparation of polypeptides within the claims. Further, given the extension prior art literature regarding the cloning and purification of CD11b and given the detailed description of the preparation of CD11b A domain variants in the present, Applicant concluded that the claims are enabled.

However, besides the polypeptide of SEQ ID NO: 1, wherein Ile at amino acid 189 has been replaced by Gly or Ala, the specification does not teach what amino acid can replace the Ile at position 189 without affecting the polypeptide's function.

8. Claim 51 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action mailed 12/3/04.

While Applicant is in possession of a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 1, wherein the Ile at amino acid 189 has been replaced by amino acid Gly or Ala, Applicant is not in possession of a purified polypeptide "comprising the amino acid sequence of SEQ ID NO: 1, wherein the Ile at amino acid 189 has been replaced by any "amino acid" other than Ile in claim 51, wherein Ile at amino acid 189 has been replaced by Gly in claim 52 or Ala in claim 53.

Applicant's arguments, filed 6/6/05, have been fully considered, but have not been found convincing.

Applicant asserts that the specification explains, the experiments together with the detailed structural studies described in the application are evidence that the Ile at 332 is critical for maintaining the "closed" or low affinity conformation of CD11b.

However, the specification provided only two Gly or Ala replacement of the critical Ile allows CD11b to be in the "open" or high affinity conformation. The claims recite any amino acid (whether naturally occurring or non common amino acid) replacement allows CD11b to be in the open conformation. The skilled artisan cannot envision all these replacement would lead to a high affinity conformation of the claimed polypeptide.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.  
Patent Examiner  
August 16, 2005

  
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